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*Admitted only in Maryland *Admitted only in Virginia •Practice Limited to Federal Agencies

July 8, 2003

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Appl. No. 10/005,876; Filed: December 7, 2001

For: Methods and Compositions for Synthesis of Nucleic Acid Molecules

Using Multiple Recognition Sites

Inventors:

CHESNUT et al.

Our Ref:

0942.5340002/RWE/BJD/JKM

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TECH CENTER 1600/2900

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. First Supplemental Information Disclosure Statement;
- 2. List of cited references on Form PTO-1449 (102 sheets);
- 3. A copy of each reference cited on Form PTO-1449 (346 documents: AL1-AL9, and AR1-AS102); and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f202.371.2540: www.skqf.com

Commissioner for Patents July 8, 2003 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

BJD/JKM/acr Enclosures

SKGF_DC1:152096.1

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IN THE UNITED STATES PATENT AND TRADEMARK DEFICE

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In re application of:

Chesnut et al.

Appl. No. 10/005,876

Filed: December 7, 2001

For:

Methods and Compositions for

Synthesis of Nucleic Acid **Molecules Using Multiple**

Recognition Sites

Art Unit:

1645

Examiner:

To Be Assigned

Atty. Docket: 0942.5340002/RWE/BJD/JKM

First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed electronically herewith, in connection with the above-captioned application. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, concise explanation of the relevance of the non-English language documents AO6 and AM7 cited on Form PTO 1449:

Document AO6, WO 98/53056, is in the German language. An unverified English language abstract of document AO6 is attached as document AT100.

Document AM7, WO 99/25851, is in the Japanese language. An unverified English language abstract of document AM7 is attached as document AR101.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

- 2 -

information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

Date: July 8, 2003

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FOREIGN PATENT DOCUMENTS EXAMINER DOCUMENT NUMBER DATE COUNTRY CLASS SUB-CLASS TRANSLATION INITIAL Yes AL1 EP 0 160 571 11/06/1985 Europe No Yes AM1 EP 0 220 009 04/29/1987 Europe No Yes

EP 0 300 422 01/25/1989 Europe No Yes WO 90/11375 10/04/1990 WIPO No Yes 03/07/1991 WIPO No WO 91/02801 OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Abremski, K., and Gottesman, S., "Purification of the Bacteriophage λ xis Gene Product Required for A Excisive Recombination," J. Biol. Chem. 257:9658-9662, AR 1 The American Society of Biological Chemists (1982). Abremski, K., and Hoess, R., "Bacteriophage P1 Site-specific Recombination. Purification and Properties of the Cre Recombinase Protein, " J. Biol. Chem. AS 1

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259:1509-1514, The American Society of Biological Chemists (1984).

DATE CONSIDERED EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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	AL2	EP 0	427 074	05/15/1991	Europe			Yes No	
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	AM2	WO 9	01/09957	07/11/1991	WIPO			No	
	AN2	WO 9	1/16427	10/31/1991	WIPO			Yes No	
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	A02	WO 9	2/15694	09/17/1992	WIPO			No	
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	AR	2.	Recombination	n: Evidence	tudies on the Pr for Topologicall 1301-1311, The M	y Unlinked Pro	ducts Follow	ic	
	AS	2 .	Adams, D.E., Mechanistic Academic Pre	Differences	e- <i>lox</i> Recombinat from the <i>in Vit</i> r	tion in Escherico Reaction," C	chia coli Ce . Mol. Biol.	ells. 226:661-673,	
	AT	2			mediated somatio			on in mice,"	

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	AL3	WO 9	2/22650	12/23/1992	WIPO			Yes No			
	АМЗ	EP 0	542 466	05/19/1993	Europe			Yes No			
	AN3	WO 9	3/15191	08/05/1993	WIPO			Yes No			
	A03	WO 9	3/19172	09/30/1993	WIPO			Yes No			
	AP3	WO 9	4/03624	02/17/1994	WIPO			Yes No			
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	AR	<u>3</u>	Chromatid Ex	Aladjem, M.I., et al., "Positive Selection of FLP-Mediated Unequal Sister Chromatid Exchange Products in Mammalian Cells," Mol. Cell. Biol. 17:857-861, American Society for Microbiology (1997).							
	AS	<u>3</u>	Albert, H., lox sites pl Ltd. (1995).	Albert, H., et al., "Site-specific integration of DNA into wild-type and mutant lox sites placed in the plant genome, " Plant J. 7:649-659, Blackwell Science Ltd. (1995).							
	AT	Andrews, B.J., et al., "Interaction of the FLP Recombinase of the Saccharomyces cerevisiae 2µm Plasmid with Mutated Target Sequences," Mol. Cell. Biol. 6:2482-2489, American Society for Microbiology (1986).									
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	AL4	CA 2	,141,412	02/17/1994	Canada			Yes No		
	AM4	WO 9	4/09127	04/28/1994	WIPO			Yes No		
	AN4	WO 9	4/17176	08/04/1994	WIPO			Yes No		
	A04	WO 9	4/18333	08/18/1994	WIPO			Yes No		
	AP4	WO 9	5/00555	01/05/1995	WIPO			Yes No		
		OI	THER (Includin	g Author, Ti	tle, Date, Pertinent Pa	ges, etc	z.)			
	AR	4		Andrews, B.J., et al., "The FLP Recombinase of the 2μ Circle DNA of Yeast: Interaction with Its Target Sequences," Cell 40:795-803, The MIT Press (1985).						
	AS	4	regulated ge	ngelastro, J.M., et al., "Identification of diverse nerve growth factor- egulated genes by serial analysis of gene expression (SAGE) profiling," Proc. atl. Acad. Sci. USA 97:10424-10429, National Academy of Sciences (September 000).						
	AT	4	Angrand, P.O., et al., "Inducible expression based on regulated recombination: a single vector strategy for stable expression in cultured cells," Nucl. Acids Res. 26:3263-3269, Oxford University Press (1998).							
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	ATTY. DOCKET NO. 0942.5430002/RWE/BJD/JKM	APPLICATION NO. 10/005,876			
FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	APPLICANT Chesnut et al.				
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	AL5	WO 9	6/04393	02/15/1996	WIPO			Ye:	
	AM5	WO 9	6/30498	10/03/1996	WIPO			Ye N	
	AN5	WO 9	6/40724	12/19/1996	WIPO			Ye: No	
	A05	WO 9	7/06265	02/20/1997	WIPO			Ye: Ne	
	AP5	WO 9	7/09436	03/13/1997	WIPO			Ye: No	
-		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent E	Pages, etc	:.)		
	AR	<u>5</u>	Anton, M., and Graham, F.L., "Site-Specific Recombination Mediated by an Adenovirus Vector Expressing the Cre Recombinase Protein: a Molecular Switch						
	AS	<u>5</u>	Araki, H., et al., "Site-specific Recombinase, R, Encoded by Yeast Plasmid pSR1," J. Mol. Biol. 225:25-37, Academic Press (1992).						
	AT	<u>5</u>			integrase family of si d global diversity," E				
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ATTY. DOCKET NO. APPLICATION NO. 0942.5430002/RWE/BJD/JKM 10/005,876

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Chesnut et al.

FILING DATE
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APPLICATION NO. 10/005,876

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	AL6	WO 9	7/25446	07/17/1997	WIPO			Yes No			
	АМб	WO 9	7/32481	09/12/1997	WIPO	o		Yes No			
	AN6	WO 9	8/10086	03/12/1998	WIPO			Yes No			
	A06	WO 9	8/53056	11/26/1998	WIPO			Yes X No			
	AP6	WO 9	9/10488	03/04/1999	WIPO			Yes No			
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	AR	<u>6</u>	attB Sites for Recombination	com the <i>Haemo</i> n-Deficient <i>H</i>	"Site-Specific Recombina ophilus influenzae Bacte Escherichia coli," J. Ba cobiology (1989).	riophag	e HP1 Propag	gated in			
	AS	<u>6</u>	Atlung, T., et al., "A versatile method for integration of genes and gene fusions into the λ attachment site of Escherichia coli," Gene 107:11-17, Elsevier Science B.V. (1991).								
	АТ	<u>6</u>	Ausubel, F.M Biology, Ausu 1.5.4 (1994)	ubel, F.M., e	Maps of Plasmids," in <i>Cu</i> et <i>al</i> ., eds., John Wiley	rrent P & Sons	rotocols in , Boston, M	Molecular A, pp. 1.5.3-			
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	ATTY. DOCKET NO. 0942.5430002/RWE/BJD/JKM	APPLICATION NO. 10/005,876
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	AM7	WO 9	9/25851	05/27/1999	WIPO			Yes X No	
	AN7	WO 9	9/55851	11/04/1999	WIPO			Yes No	
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	AR	OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Ausubel, F.M., et al., "Mutagenesis by the Polymerase Chain Reaction," in Current Protocols in Molecular Biology, Ausubel, F.M., et al., eds., John Wiley & Sons, Boston, MA, pp. 8.5.1-8.5.9 (1991).							
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	AT	7	Purification	of the Prote. Biol. Chem.	ne FLP Protein of the 2- ein from <i>Escherichia col</i> . <i>260</i> :12313-12319, The A	i Cells	Expressing	the Cloned	
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	AN8	WO 0	1/07572	02/01/2001	WIPO			Yes No		
	A08	wo o	1/11058	02/15/2001	WIPO			Yes No		
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	AR	<u>39</u>	Hoekstra, M. Manipulation	F., et al., s in Yeast,"	"Shuttle Mutagenesis: Ba Meth. Enzymol. 194:329-	cterial 342, Ac	Transposon ademic Pres	s for Genetic s (1991).
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	AT	39	Acids and Mo	lecular Biol	i, K., "The Cre- <i>lox</i> Reco ogy, Volume 4, Eckstein, Germany, pp 99-109 (199	F., an		
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	AR	<u>41</u>		ing sites," I	site-specific recombina Proc. Natl. Acad. Sci. U					
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	AS	<u>51</u>	Factor Inter	actions with	cic Analysis of <i>Escheric</i> Its Bacteriophage λ Η' American Society for Mic	Recogni	tion Site,"	on Host J.
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	AR	<u>52</u>	substitution	s by a site-	neration of single base specific recombination al Academy of Sciences	system,"				
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	AR	<u>67</u>	Site-Specifi	c Recombinat:	"Seed-Specific Gene Activation Mediated by the Cre/lox nation System," Plant Physiol. 106:447-458, American iologists (1994). "In vivo cloning of PCR products in E. coli," Nucl. Acids ford University Press (1993).					
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	AT	67	Orban, P.C., mice, " Proc. (1992).	et al., "Ti Natl. Acad.	ssue- and site-specific Sci. USA 89:6861-6865,	DNA rec	ombination l Academy o	in transgenic f Sciences		
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	AS	<u>68</u>	Padgett, K.A., and Sorge, J.A., "Creating seamless junctions independent of restriction sites in PCR cloning," <i>Gene 168</i> :31-35, Elsevier Science B.V. (1996).					
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	AS	<u>70</u>	Patel, P.H., and Loeb, L.A., "DNA polymerase active site is highly mutable: Evolutionary consequences," Proc. Natl. Acad. Sci. USA 97:5095-5100, Nation Academy of Sciences (May 2000).					
	AT	<u>70</u>	baculoviruse	s by enzymat:	Highly efficient general ically mediated site-spe 500, Oxford University	ecific i	n vitro rec	
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	AS	72	Pichel, J.G., et al., "Timing of SV40 oncogene activation by site-specific recombination determines subsequent tumor progression during murine lens development," Oncogene 8:3333-3342, Macmillan Press (1993).					
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	AR	73	Podhajska, A	.J., et al., vivo: const	, "Control of cloned gene cruction of the heat-puls 3, Elsevier Science (1985	expres	sion by pro	
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	AR	74	Prasad, P.V., et al., "Substrate Recognition by the 2μm Circle Site-Specific Recombinase: Effect of Mutations within the Symmetry Elements of the Minima					
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	AS	75	Qin, M., et al., "Cre recombinase-mediated site-specific recombination between plant chromosomes," Proc. Natl. Acad. Sci. USA 91:1706-1710, National Academy of Sciences (1994).					
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	AS	90	Strathmann, Acad. Sci. U	M., et al., SA 88:1247-1:	"Transposon-faci 250, National Ac	litated I	ONA sec Scienc	quencing," <i>P.</i> ces (1991).	roc. Natl.
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